

# PATENT COOPERATION TREATY

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From the INTERNATIONAL SEARCHING AUTHORITY

To: GEOFFREY L. MELNICK G.E. EHRLICH (1995) LTD. 11 MENACHEM BEGIN STREET RAMAT GAN, ISRAEL 52 521	<b>RECEIVED</b>  05 JUL 2005  FILE No. 27840 <b>G.E. EHRLICH (1995) LTD.</b>
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**PCT**

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT AND  
THE WRITTEN OPINION OF THE INTERNATIONAL  
SEARCHING AUTHORITY, OR THE DECLARATION  
(PCT Rule 44.1)

Date of mailing (day/month/year) **22 JUN 2005**

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Applicant's or agent's file reference 27840	<b>FOR FURTHER ACTION</b> See paragraphs 1 and 4 below
International application No. PCT/IL04/00641	International filing date (day/month/year) 15 July 2004 (15.07.2004)
Applicant DUNE MEDICAL DEVICES LTD.	

1.  The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

**Filing of amendments and statement under Article 19:**

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

**When?** The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

**Where?** Directly to the International Bureau of WIPO, 34 chemin des Colombettes  
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

**For more detailed instructions,** see the notes on the accompanying sheet.

2.  The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3.  With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

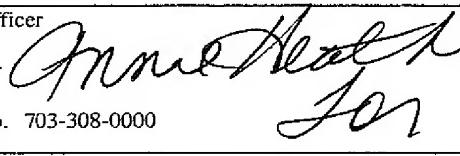
Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Brian Casler  Telephone No. 703-308-0000
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## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 27840	<b>FOR FURTHER ACTION</b>	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/IL04/00641	International filing date ( <i>day/month/year</i> ) 15 July 2004 (15.07.2004)	(Earliest) Priority Date ( <i>day/month/year</i> ) 24 July 2003 (24.07.2003)
Applicant DUNE MEDICAL DEVICES LTD.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 1 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the Report**

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b.  With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2.  Certain claims were found unsearchable (See Box No. II)

3.  Unity of invention is lacking (See Box No. III)

4. With regard to the title,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

5. With regard to the abstract,

the text is approved as submitted by the applicant.

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 1

as suggested by the applicant.

as selected by this Authority, because the applicant failed to suggest a figure.

as selected by this Authority, because this figure better characterizes the invention.

- b.  none of the figures is to be published with the abstract.

**INTERNATIONAL SEARCH REPORT**

International application No.

PCT/IL04/00641

**Box IV TEXT OF THE ABSTRACT (Continuation of Item 5 of the first sheet)**

A method and apparatus for examining a substance volume to characterize its type, particularly useful for examining tissue to characterize it as cancerous or non-cancerous, as shown, by applying a polarizing magnetic field through the examined substance; applying RF pulses locally to the examined substance volume such as to invoke electrical impedance (EI) responses signals corresponding to the electrical impedance of the substance, and magnetic resonance (MR) responses signals corresponding to the MR properties of the substance; detecting the EI and MR response signals; and utilizing the detected response signals for characterizing the examined substance volume type.

**INTERNATIONAL SEARCH REPORT**

International application No.

PCT/IL04/00641

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) : A61B 5/05; G01V 3/00  
US CL : 600/411, 547; 324/309

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/411, 421, 422, 423, 547; 324/309

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

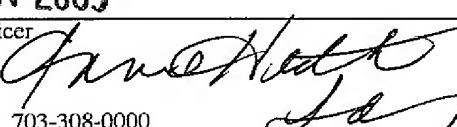
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,397,095 B1 (EYUBOGLU et al) 28 May 2002 (28.05.2002), column 1, lines 25-30, 39-46, column 2, lines 13-17 and 61-67, column 3, lines 1-6, column 4, lines 21-39, column 5, lines 46-48 and column 6, lines 31-40.	1, 3, 11, 16, 18, 41, 43, 48
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Y	US 5,735,278 A (HOULT et al) 7 April 1998 (7.4.1998), column 2, lines 38-44, column 3, lines 25-37, column 4, lines 26-31 and column 9, lines 24-37.	2, 4-10, 12-15, 17, 19-40, 42, 44-47, 49
Y	US 4,689,567 A (MAUDSLEY) 25 August 1987 (25.8.1987), column 1, lines 62-68, column 2, lines 1-3 and column 5, lines 55-62.	4, 9, 19, 38
Y,E	US 6,766,185 B2 (SCOTT) 20 July 2004 (20.7.2004), column 1, lines 27-30, column 2, lines 28-41, 48-55 and 63-67, column 3, lines 1-9 and 25-28, column 4, lines 36-38 and column 5, lines 21-30 and 37-48.	5, 6, 20-28, 32-35, 45
Y	US 2001/0051774 A1 (LITTRUP et al) 13 December 2001 (13.12.2001), paragraph 4, lines 4-10 and paragraph 57, lines 1-30.	7, 10, 15, 36, 39, 40
Y	US 5,758,646 A (VAN DER MEULEN et al) 2 June 1998 (2.6.1998), column 2, lines 6-16 and 25-34 and abstract.	8, 37

<input checked="" type="checkbox"/>	Further documents are listed in the continuation of Box C.	<input type="checkbox"/>	See patent family annex.
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* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search  25 May 2005 (25.05.2005)	Date of mailing of the international search report  <b>22 JUN 2005</b>
Name and mailing address of the ISA/US  Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450  Facsimile No. (703) 305-3230	Authorized officer  Brian Casler  Telephone No. 703-308-0000

**INTERNATIONAL SEARCH REPORT**

International application No. PCT/IL04/00641	
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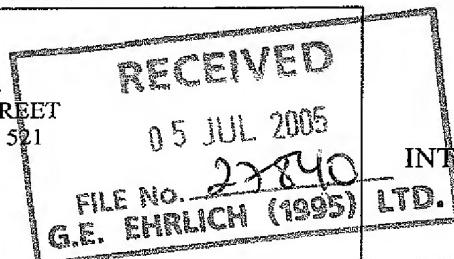
**C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y,P	US 2003/0199753 A1 (HIBNER et al) 23 October 2003 (23.10.2003), paragraph 21, lines 1-11, paragraph 23, lines 1-10, paragraph 80, lines 5-7, paragraph 82, lines 7-43 and paragraph 83, lines 1-4.	12, 14, 42, 44, 46, 47
Y	US 5,442,290 A (CROOKS) 15 August 1995 (15.8.1995), column 4, lines 61-68 and column 5, lines 1-3.	13, 14, 49
Y	US 4,751,464 A (BRIDGES) 14 June 1988 (14.6.1998), column 3, lines 3-29, column 6, lines 50-68 and column 7, lines 1-10.	27, 28
A	US 4,625,171 A (SEKIHARA et al) 25 November 1986 (25.11.1986), column 1, lines 42-44.	2, 17, 29-31

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
GEOFFREY L. MELNICK  
G.E. EHRLICH (1995) LTD.  
11 MENACHEM BEGIN STREET  
RAMAT GAN, ISRAEL 52521



# PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis. 1)

Applicant's or agent's file reference  27840	Date of mailing (day/month/year) <b>22 JUN 2005</b>	
International application No.  PCT/IL04/00641	International filing date (day/month/year)  15 July 2004 (15.07.2004)	Priority date (day/month/year)  24 July 2003 (24.07.2003)
International Patent Classification (IPC) or both national classification and IPC  IPC(7): A61B 5/05; G01V 3/00 and US Cl.: 600/411, 547; 324/309		
Applicant  DUNE MEDICAL DEVICES LTD.		

**1. This opinion contains indications relating to the following items:**

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

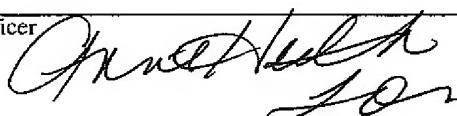
**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

**3. For further details, see notes to Form PCT/ISA/220.**

Name and mailing address of the ISA/ US  Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  Brian Casler  Telephone No. 703-308-0000
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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/IL04/00641

**Box No. I Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
 This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material
    - a sequence listing
    - table(s) related to the sequence listing
  - b. format of material
    - in written format
    - in computer readable form
  - c. time of filing/furnishing
    - contained in international application as filed.
    - filed together with the international application in computer readable form.
    - furnished subsequently to this Authority for the purposes of search.
3.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/IL04/00641

**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)      Claims Please See Continuation Sheet      YES  
                      Claims Please See Continuation Sheet      NO

Inventive step (IS)      Claims Please See Continuation Sheet      YES  
                      Claims Please See Continuation Sheet      NO

Industrial applicability (IA)      Claims Please See Continuation Sheet      YES  
                      Claims Please See Continuation Sheet      NO

**2. Citations and explanations:**

Please See Continuation Sheet

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/IL04/00641

**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 30-34 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because Claims 30-34 are indefinite for the following reason(s): there is no antecedent basis for the term "said transmission line."

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/IL04/00641

**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

**V.1. Reasoned Statements:**

The opinion as to Novelty was positive (Yes) with respect to claims 2, 4-10, 12-15, 17, 19-40, 42, 44-47, 49

The opinion as to Novelty was negative (No) with respect to claims 1, 3, 11, 16, 18, 41, 43, 48

The opinion as to Inventive Step was positive (Yes) with respect to claims 5, 6, 10, 12, 14, 20-28, 32-35, 42, 44-47

The opinion as to Inventive Step was negative (NO) with respect to claims 1-4, 7-9, 11, 13, 15-19, 29-31, 36-41, 43, 48, 49

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-49

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE

**V. 2. Citations and Explanations:**

Claims 1, 3, 11, 16, 18, 41, 43 and 48 lack novelty under PCT Article 33(2) as being anticipated by Eyuboglu et al. (U.S. Patent No. 6,397,095).

Eyuboglu et al. teaches a method of examining a substance volume to characterize its type, including applying a magnetic field and RF pulses to the volume to produce electrical impedance and magnetic resonance response signals, detecting those signals, using the detected signals to characterize the type of substance examined, where the electrical impedance signals are used to determine the effective electrical impedance of the volume and where the magnetic resonance signals are nuclear magnetic resonance signals, and an apparatus for implementing that method, including means for applying a magnetic field through the volume, a probe, which includes a current sensor for sensing the current passing through the volume, and an electrical control and processing system, which includes an indication of the type of substance volume examined (col. 1, lines 25-30 and 39-46, col. 2, lines 13-17 and 61-67, col. 3, lines 1-6, col. 4, lines 21-39, col. 5, lines 46-48 and col. 6, lines 31-40). Here, the Examiner has interpreted the electrodes of the reference as a probe of the present application.

Claims 2, 17 and 29-31 lack an inventive step under PCT Article 33(3) as being obvious over Eyuboglu et al. in view of Hoult et al. (U.S. Patent No. 5,735,278).

Eyuboglu et al. teaches all of the features of the present invention except for explicitly disclosing that the polarizing magnetic field is varied to vary the response signals by movement of the magnet, where the magnet is a permanent magnet and the movement is caused by an air-filled cylinder and controlled by the electrical control system. In the same field of endeavor, Hoult et al. teaches that a magnetic field may be varied by movement of the magnet, where the movement is caused by a hydraulic cylinder system, controlled by an electrical control system (col. 3, lines 25-37, col. 4, lines 26-31 and col. 9, lines 24-37). Although Hoult et al. does not specifically disclose that the magnet is a permanent magnet, it is well-known in the art that a magnetic field may be generated by any of a permanent magnet, a superconducting magnet or a resistive magnet (see, e.g., Sekihara et al. (U.S. Patent No. 4,625,171), col. 1, lines 42-44). It would have been obvious to one of ordinary skill in the art at the time of the invention to have moved the magnet in order to change the magnetic field without the need for movement of the volume being examined (see for motivation Hoult et al. at col. 2, lines 38-44).

Claims 4, 9, 19 and 38 lack an inventive step under PCT Article 33(3) as being obvious over Eyuboglu et al. in view of Maudsley (U.S. Patent No. 4,689,567).

Eyuboglu et al. teaches all of the features of the present invention except for expressly disclosing that the RF pulses produce MR free induction decay (FID) signals, which are detected and utilized in characterizing the tissue, and that the detected MR signals are analyzed for spin density, longitudinal relaxation time or transverse relaxation time. In the same field of endeavor, Maudsley teaches an MR system in which the RF pulses produce FID signals that are used to produce an image of the examined volume and where the response signals are analyzed to determine the transverse relaxation time of the volume (col. 1, lines 62-68, col. 2, lines 1-3 and col. 5, lines 55-62). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the techniques of Maudsley in the method of Eyuboglu et al. in order to increase the contrast of the results (see Maudsley at col. 1, lines 65-68).

Claims 7, 10, 15, 36, 39 and 40 lack an inventive step under PCT Article 33(3) as being obvious over Eyuboglu et al. in view of Littrup et al. (U.S. Patent Application Publication No. 2001/0051774).

Eyuboglu et al. teaches all of the features of the present invention except for expressly disclosing that the detected response

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

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**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

signals are collected and analyzed for predetermined parameters characterizing the substance type and comparing the predetermined parameters with corresponding parameters of known substance types to produce a best match, that the parameters are modeled into a set and classified according to the known substance types and that a determination of whether the substance volume is cancerous or non-cancerous is made. In the same field of endeavor, Littrup et al. teaches a system using electrical impedance analysis, and may also include magnetic resonance imaging, where tissue types are analyzed and characterized according to a set of parameters, those parameters are modeled into a representation of the tissue type, compared to reference tissue types and where the system is used to determine the presence of cancer in the tissue (para. 4, lines 7-10 and para. 57, lines 1-30). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the methods of Littrup et al. in the system of Eyuboglu et al. in order to provide a safe, reliable and low-cost analysis of tissue pathologies (see for motivation Littrup et al. at para. 4, lines 4-7).

Claims 8 and 37 lack an inventive step under PCT Article 33(3) as being obvious over Eyuboglu et al. in view of Van Der Meulen et al. (U.S. Patent No. 5,758,646).

Eyuboglu et al. teaches all of the features of the present invention except for expressly disclosing that the sequence of pulses has some pulses optimized for the electrical impedance responses and some for the magnetic resonance responses. In the same field of endeavor, Van Der Meulen et al. teaches a system where different RF pulses within a sequence are optimized according to the parameters of the response that they intend to target (col. 2, lines 6-16 and 25-34). It would have been obvious to one of ordinary skill in the art at the time of the invention to have optimized the RF pulses of Eyuboglu et al. in order to reduce the number of sequences from which an operator must select and to adapt the sequences to the particular response sought (see for motivation Van Der Meulen et al., abstract).

Claims 13 and 49 lack an inventive step under PCT Article 33(3) as being obvious over Eyuboglu et al. in view of Crooks (U.S. Patent No. 5,442,290).

Eyuboglu et al. teaches all of the features of the present invention except for expressly disclosing that the magnetic resonance signals are electron magnetic resonance signals. In the same field of endeavor, Crooks teaches that a patient imaging volume may be monitored by an electron magnetic resonance detector (col. 4, lines 61-68 and col. 5, lines 1-3). It would have been obvious to one of ordinary skill in the art at the time of the invention that electron magnetic resonance signals could have been used instead of nuclear magnetic resonance signals because each is a suitable method of providing an image of a substance volume.

Claims 5, 6, 12, 14, 20-28, 32-35, 42 and 44-47 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the transmission line features and tissue analysis system as described.

Claims 1-49 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

## NOTESTOFORMPCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

#### What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

**When ?** Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

**How ?** Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

**The amendments must be made in the language in which the international application is to be published.**

#### What documents must/may accompany the amendments ?

##### Letter (Section 205(h)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

**The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.**